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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,577	04/02/2004	Shilpa S. Thosar	3168/7/US	3792

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/817,577

Applicant(s)

THOSAR ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37, 45-47, 57-61 and 73-76 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37, 45-47, 57-61 and 73-76 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of amendment and remarks all dated 4-1-05 is acknowledged.

Claims 1-37,45-47,57-61 and 73-76 are pending in the case.

Response to Arguments

Applicant's arguments with respect to claims 1-37,45-47,57-61 and 73-76 have been considered but are moot in view of the new ground(s) of rejection.

Instant claims have been amended to delete the word "micronized" and the claims as amended are directed to a pharmaceutical composition comprising eplerenone.

Claim Rejections - 35 USC § 103

Claims 1-37,45-47,57-61 and 73-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,559,332 to Grob et al (Grob) in view of Remington: the science and practice of Pharmacy (vol. 2, 1995, hereafter Remington).

Grob teaches spiroxanes and analogues of spiroxanes for the treatment of hyperaldosteronism and the diseases associated with the same (applicants admit the same in page 1 of the specification). The specific compounds in col. 3, lines 5-10 of Grob reference reads on the instant eplerenone compounds. Grob teaches administering the composition for upto 2 daily dosage units (col. 15, lines 25-35). Further, Grob teaches oral tablet preparation or capsule preparations that incorporate the claimed diluents, disintegrants, wetting agents etc (col. 28) such as sorbitol, magnesium stearate, celluloses, talc, starch, gelatin etc. As applicants admitted in the instant specification, Grob does teach the instant eplerenone compounds. However,

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Grob does not teach a composition comprising eplerenone in the claimed amounts and also fails to teach an immediate release composition. However, Grob teaches both tablet and capsule compositions, as unit dosage compositions incorporating specifically the claimed disintegrant such as microcrystalline cellulose, glidants- magnesium stearate, binders, diluents such as lactose etc (examples).

Remington teaches the preparation of tablets, capsules and other oral dosage forms where the claimed binders, lubricants, disintegrants, glidants etc., are routinely employed as pharmaceutical excipients in preparing the dosage forms (pages 1616-1620, 1642). The dosage forms are prepared by known methods such as wet granulation, compaction etc (page 1623-1628 and examples on pages 1636-1637). Remington also teaches film coating for modifying the release rate of the pharmaceutically active agents (1653-1654).

Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a pharmaceutical composition comprising eplerenone from the teachings of Grob, by adding the art recognized pharmaceutical excipients (Remington), with an expectation to achieve the desired pharmacological activity because Remington teaches inclusion of different excipients depending on the desired release of the drug or active agent and also employing different methods for preparing the dosage forms i.e., compression, granulation, coating the tablet for a modified release rate etc. While Grob does not teach the exact percentages or amounts of the carrier materials, optimization within prior art conditions through experimentation

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so as to achieve the desired release rate would have been within the scope of a skilled artisan.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

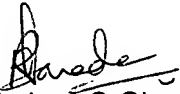
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM.

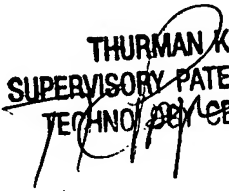
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lakshmi S Channavajjala
Examiner
Art Unit 1615

June 14, 2005


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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